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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/522,900	03/10/2000	Alison A. McCormick	LSB-001	4521

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EXAMINER	
BLANCHARD, DAVID J	

ART UNIT	PAPER NUMBER
1643	

DATE MAILED: 06/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/522,900	MCCORMICK ET AL.	
	Examiner	Art Unit	
	David J. Blanchard	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 April 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6-23,29,37-40 and 54-57* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6-23,29,37-40 and 54-57* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on ____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 5, 24-28, 30-36 and 41-53 have been cancelled.

Claims 1-3 and 54-55 have been amended.

Claims 57 has been added.

2. Claims 1-4, 6-23, 29, 37-40 and 54-56 are pending and under examination.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Objections/Rejections Withdrawn

4. The objection to claim 55 under 37 CFR 1.75(c) as being of improper dependent from for failing to further limit the subject matter of a previous claim is withdrawn in view of the amendment to the claim.

5. The rejection of claims 1-4, 6-23, 29, 37-40, 54 and applied to newly added claims 55-56 under 35 U.S.C 112, second paragraph, as being indefinite in the recitation of "encoded at least in part" is withdrawn in view of the amendments to the claims.

6. The rejection of claim 23 under 35 U.S.C 112, second paragraph, as being indefinite in the recitation of "at least about" is withdrawn in view of that the claim recites a minimal amount of polypeptide to be used.

7. The rejection of claims 1-4, 6-23, 29, 37-40, 54 and applied to newly added claims 55-56 under 35 U.S.C 112, second paragraph, as being indefinite in the

recitation of "a nucleic acid encoding a peptide sequence overlapping a peptide sequence encoded by said nucleic acid in the cells of said tumor" is withdrawn in view of the amendments to the claims.

8. The rejection of claim 56 under 35 U.S.C. 103(a) as being unpatentable over Caspar et al (Blood, 90(9):3699-3706, November 1997) in view of Fiedler et al (Immunotechnology, 3(3):205-216, October 1997, Ids filed 3/8/04) and Tang et al (Journal of Biological Chemistry, 271(26):15682-15686, June 1996) and Hakim et al (Journal of Immunology, 157:5503-5511, 1996) is withdrawn upon further consideration.

Response to Arguments

9. The rejection of claims 1-4, 6-23, 29, 37-40, 54-56 and applied to newly added claim 57 under 35 U.S.C. 112, first paragraph because the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims is maintained.

The response filed 4/24/2006 argues that the applied art of Casper et al and Hawkins et al refer to their compositions as vaccines and there is no guarantee that a vaccine can prevent or cure anything 100% of the time. From previous published vaccines for non-Hodgkin's B-cell lymphomas, and the data demonstrating the compositions used in the invention induce an immune response, the use of the term "vaccine" is appropriate and the rejection should be withdrawn. This has been fully considered but is not found persuasive. Again, the issue is not whether the

administration of the claimed polypeptide self-antigen will elicit an anti-B cell lymphoma immune response, the issue is whether or not administering the claimed polypeptide self-antigen can prevent or cure B-cell lymphomas in a patient that has or is at risk of getting B-cell lymphoma. While the term "vaccine" embraces varying degrees of efficacy, the term also carries a connotation of preventing B-cell lymphoma in subjects that do not yet have cancer, as well as completely curing cancer and preventing relapse. Further, applicants base claim, claim 1, still recites a subject "at risk of developing the B-cell lymphoma tumor", which clearly encompasses treating a person who does not yet have cancer, as well as completely curing cancer and preventing any relapse. It remains on this record that there is no teaching in the prior or post-filing art or in applicant's specification indicating that B-cell lymphomas can be prevented or cured, thus indicating the high degree of unpredictability of preventing and curing cancer. Further, applicant's argument for the claimed polypeptide and its use as a B-cell lymphoma tumor specific vaccine is curious in view of applicant's statement at pg. 12 of the response, which states: "While one may dream such a thing is possible, the world of vaccines is full of failed attempts and unpredictability." Applicant is again invited to amend the claims to recite a "composition" or "therapeutic composition" for the term "vaccine" in the interest of compact prosecution or provide documentary evidence that administration of the claimed polypeptide self-antigen prevents or cures B-cell lymphomas as broadly embraced by the claims.

10. The rejection of claims 1-4, 6-23, 29, 37-40, 54-56 and applied to newly added claim 57 under 35 U.S.C. 112, first paragraph because the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims is maintained.

The response filed 4/24/2006 has been carefully considered, but is deemed not to be persuasive. The response argues that the data in the specification as well as the data in the prior art of record demonstrate that appropriate immune responses can be generated without the entire heavy and light chain and without being in the "context of framework sequences". Applicant appears to argue that the exemplified molecules, which are single-chain antibodies (i.e., heavy and light chain variable regions linked by a short peptide linker) are different from the naturally occurring tumor antigen, i.e., the whole immunoglobulin expressed on the surface of the B cells. The examiner acknowledges that the single-chain antibodies are different from the immunoglobulins expressed on the surface of B cells, however, the rejection did not question the use of single chain antibodies to mimic the idiotypes of the surface immunoglobulins on B cell lymophomas. In fact, as communicate din the previous office action "Applicant is enabled for a scFv idiotype composition comprising both VH and VL domains obtained from lymphoma cells of a subject, which mimic the natural idiotype expressed on the surface of B-cell lymphomas." (bottom of pg. 11 of the office action mailed 10/24/2005). Further, while applicant asserts that the data in the specification as well as data in the prior art demonstrate that appropriate immune responses can be generated without the

entire heavy and light chain and without being in the "context of framework sequences", applicant has not directed the examiner to any data in the specification (i.e., page and/or line numbers) or in the prior art in support of the assertion that an anti-idiotypic antibody response elicited against an epitope of a surface immuoglobulin, an epitope of a V region or part of the VH and VL domains, or one CDR (i.e., CDR2) effectively mimics the natural idiotype of the surface immunoglobulin expressed in B-cell lymphomas in view of the opposing evidence cited by the examiner (Casper et al and Benvunuti et al). Further, applicant's arguments are inconsistent with the teachings of their own specification, which indicates that an idiotype is formed by the association of the hypervariable or complementary determining regions of the VH and VL domains (see page 16 of the specification) and at page 51, lines 7-10, it states: "However, because most idiotypes are expected to be the result of the interaction of the VH with the VL domain, more preferred compositions combine both these regions." Yet the claims remain drawn to a polypeptide self-antigens that only comprise an epitope of a surface immuoglobulin (i.e., short peptide sequence of a surface immunoglobulin), or an epitope of a V region (i.e., part of a CDR or part of a FR), or part of the VH and VL domains, or just one CDR (i.e., CDR2).

Applicant acknowledges that the art of Benvenuti et al (cited previously in the Office Action mailed 8/17/04) provides evidence that one variable chain alone is not an effective antigen and applicant goes on to argue that this is not what applicant claims. This has been fully considered but is not found persuasive. Again, the present claims still broadly encompass a polypeptide self-antigen that includes an epitope or epitopes

of a surface immunoglobulin. Claim 1 still encompasses using any epitope(s) from the constant region or the hinge or the frameworks or the CDRs, which would not produce an idiotype that mimics the natural surface Ig expressed on B-cell lymphomas. Further, the claims still encompass an idiotypic epitope of a single V region (i.e., part of a CDR or part of a FR), of any two V region domains (i.e., VH-VH pair), and of only part of the VH and only part of the VL domains, which encompasses incomplete VH and VL pairs. Applicant has not provided any objective evidence that epitopes from the constant regions or hinge region or frameworks, or from a single V region, or from just any two V regions (i.e., VH-VH or VL-VL) or from only part of the VH and VL domains of B-cell lymphoma surface immunoglobulins result in conformational dependent epitopes (idiotypes) mimicking the surface immunoglobulins expressed on B cell lymphomas, that effectively elicits a specific immune response against the B cell lymphomas. Further, applicant has not provided objective evidence that incomplete VH and VL scFvs connected via applicants linkers or scFvs comprising two VH domains (i.e., VH-VH) or two VL domains (i.e., VL-VL) connected via applicant's linkers result in idiotypes that mimic the natural surface Ig expressed in B-cell lymphomas. Again, Benvenuti et al (cited previously in the Office Action mailed 8/17/04) makes clear that the immune response (i.e., anti-idiotypic antibodies) is directed exclusively against conformationally combined VL/VH determinants (see page 1557, right column), which provides strong evidence that the conformationally combined VH/VL pairs are required to mimic the natural idiotype of the surface immunoglobulin expressed in B-cell lymphomas. Therefore, it is not mere speculation or a hypothesis on the part of the Examiner, but the

explicit teachings of Benvenuti et al as well as applicants specification that conformationally combined parental VH/VL pairs are required to mimic the natural idiotype of the surface immunoglobulin expressed by B-cell lymphomas. Further, Casper et al (previously cited on PTO-892 mailed 8/17/2004), state: "a change of one or two amino acids in the second complementarity-determining region (CDR2) of the heavy chain seemed to be responsible for the loss of binding to the treatment of MoAb." (anti-idiotypic antibody) (see page 3699, left column). Thus, it is unlikely that epitopes derived from any part of the surface immunoglobulin or epitopes that do not contain both VH and VL domains, would mimic the idiotypes of native surface immunoglobulins expressed in B-cell lymphomas.

Applicant's statement at pg. 11 of the response that the CDRs themselves are poorly defined hypothetical regions, not physically distinct portions of the molecule is curious, given that the CDRs have been precisely defined by Kabat since the 1980's and are well known by those skilled in the art as evidenced by Queen et al, which states "The extent of the framework region and CDR's have been precisely defined" (U.S. Patent 5,530,101, see col. 11, lines 35-41). Further, applicant's arguments are even more curious in view of the allowed claims in USSN 10/067,790, which recite "wherein the polypeptide is a single chain the first domain is the Ig VH domain and the second domain is a VL domain, both of which domains create an idiotype of a surface Ig of said B cell lymphoma, and wherein said polypeptide induces an idiotype-specific response directed to said B-cell lymphoma upon administration to a subject." (claim 51).

Again, Applicant is enabled for a scFv idiotype composition comprising both VH and VL domains obtained from lymphoma cells of a subject, which mimic the natural idiotype expressed on the surface of B-cell lymphomas.

11. The rejection of claims 54 and 56 under 35 U.S.C. 112, first paragraph as failing to comply with the written description requirement for introducing new matter is maintained.

The response filed 4/24/2006 has been carefully considered, but is deemed not to be persuasive. Applicant argues that the language 'not fused or conjugated to another polypeptide" is an accurate description of the antigens actually made in the examples. Applicant states that this language is an inherent property of the molecules made in the examples and adding such language is not new matter any more than adding language of other inherent properties such as solubility, molecular weight, ect. Further, applicant argues that following the examples in the specification would have led the skilled artisan to the claimed polypeptide not conjugated or fused to another polypeptide. This has been fully considered but is not found persuasive. It is reiterated that the disclosure of the polypeptide as being inherently immunogenic so that effective immune responses are generated without the need for fusion to another polypeptide or an adjuvant is with respect to plant expression systems and the inherent immunogenicity of the polypeptide produced thereby. The rejected claims and the base claim (claim 1) from which they depend do not require plant expression of the presently

claimed polypeptide, which confers the inherent immunogenic properties of the presently claimed polypeptide in the absence of conjugation to another polypeptide.

12. The rejection of claims 1-4, 6-13, 17-23, 29 and 38 under 35 U.S.C 102(b) as being anticipated by Casper et al (Blood, 90(9):3699-3706, November 1997) is maintained.

The response filed 4/24/2006 argues that claim 1 has been amended to require that the claimed polypeptide induce an immune response, rather than be "capable of" inducing an immune response in a mammal. Applicant again argues that the polypeptide of Casper et al is fused to GM-CSF and there is no indication that the VH-VL polypeptide alone induces an immune response. This has been carefully considered, but is deemed not to be persuasive. As previously acknowledged by applicant, Casper et al teach a scFv (adenovirus) without the GM-CSF, which when expressed in vivo induced an anti-idiotype immune response, providing evidence that the scFv induces an immune response without the need for adjuvant or other immunostimulatory material (see Figures 2 and 3) (see bridging lines of pages 10-11 of the applicant's response filed 8/2/05). Applicant is reminded that where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of anticipation has been established. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing

that they are not." In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the prima facie case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. In re Best, 562 F.2d at 1255, 195 USPQ at 433. See also Titanium Metals Corp. v. Banner, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985). See MPEP 2112 and 2112.01.

Further, applicant is again reminded that the claimed polypeptide self-antigen "includes...", which is synonymous to "comprising" and is inclusive or open-ended and does not exclude additional unrecited elements (see MPEP 2111.03), particularly in view of claim 38 which recites that the composition comprises a cytokine. Applicant also argues that a well-chosen linker is necessary to produce a functional protein and Casper only uses one linker, which is frequently unacceptable. This has been fully considered but is not found persuasive. Applicant, question the operability of the prior art, however, applicant is reminded that the arguments of counsel cannot take the place of evidence in the record. In re Schulze, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965). Examples of attorney statements which are not evidence and which must be supported by an appropriate affidavit or declaration include statements regarding unexpected results, commercial success, solution of a long-felt need, inoperability of the prior art, invention before the date of the reference, and allegations that the author(s) of the prior art derived the disclosed subject matter from the applicant. See MPEP 716.01.

Applicant also argues the inclusion of claims 2-3 in the present rejection stating that Casper produces their polypeptide in insect cells rather than in plant cells. In response to this argument applicant is reminded that "[E]ven though product-by-process

claims are limited by and defined by the process, determination of patentability is based on the product itself. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). The recitation of a process limitation in claims 2-3 is not viewed as positively limiting the claimed product absent a showing that the process of making recited in claims 2-3 imparts a novel or unexpected property to the claimed product, as it is assumed that equivalent products are obtainable by multiple routes. The burden is placed upon the applicants to establish a patentable distinction between the claimed and references products. See MPEP 2113.

13. The rejection of claims 1-4, 6-12, 17-23, 29 and 37-38 under 35 U.S.C 102(b) as being anticipated by Hawkins et al (WO 94/08008, 4/14/1994) is maintained.

The response filed 4/24/2006 argues that Hawkins et al teach immunizing with a nucleic acid and does not teach immunization with the polypeptide functions to elicit the claimed immune response. Applicant also argues that claim 1 has been amended to require that the claimed polypeptide induce an immune response, rather than be "capable of" inducing an immune response in a mammal. This has been carefully considered but is not found persuasive. It is reiterated that Hawkins et al teach a scFv that is an idiotypic determinant (i.e., epitope) of an immunoglobulin expressed on the surface of a B cell lymphoma and the scFv is purified and administration of the scFv generated an anti-idiotypic response, clearly indicating that the scFv was in correctly

folded form and mimicked the idiotype of the immunoglobulin expressed on the B cell lymphomas (see pages 19-21). Further, as above, Applicant is reminded that where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation has been established. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the prima facie case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. In re Best, 562 F.2d at 1255, 195 USPQ at 433. See also Titanium Metals Corp. v. Banner, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985). See MPEP 2112 and 2112.01.

14. The rejection of claims 1-4, 6-23, 29, 37-40, 54-55 and applied to newly added claim 57 under 35 U.S.C. 103(a) as being unpatentable over Caspar et al (Blood, 90(9):3699-3706, November 1997) in view of Fiedler et al (Immunotechnology, 3(3):205-216, October 1997, Ids filed 3/8/04) and Tang et al (Journal of Biological Chemistry, 271(26):15682-15686, June 1996) and Hakim et al (Journal of Immunology, 157:5503-5511, 1996) is maintained.

The response filed 4/24/2006 appears to argue as above against Casper et al and the examiners comments above apply here as well. Applicant argues that the art of

Hakim et al shows three different scFvs were used, one fused to GM-CSF, one to IL-1B and the third was the scFv alone. Applicant asserts that the scFv alone is similar to the presently claimed invention and this vaccine did not elicit an immune response, citing Table II and Fig. 5 of Hakim et al for support. This has been fully considered but is not found persuasive. The examiner agrees with applicant that Hakim show that the scFv alone did not elicit an immune response, Applicant's arguments are not commensurate in scope with the claims. Again, the claimed polypeptide self-antigen "includes...", which is synonymous to "comprising" and is inclusive or open-ended and does not exclude additional unrecited elements (see MPEP 2111.03). Therefore, the art still reads on the claims, particularly in view of dependent claims 37-39.

At pp. 13-14 of the response applicant argues with properties of the claimed polypeptides that are asserted to not be shared with the polypeptides of the prior art, arguing that the plant produced scFvs of Fiedler et al have the ability to bind, which is different from the ability to elicit an effective immune response and none of the references suggest using a randomized linker for a two domain polypeptide antigen and Tang et al reference attempts many linkers between domains for a single chain antibody to obtain binding ability, which applicant reiterates is much easier to obtain than mimicking an epitope for eliciting an immune response. Further, applicant states that the random linkers in Tang et al are outside the claimed properties of the linkers claimed in the dependent claims. This has been fully considered but is not found persuasive. While some of the randomized linkers of Tang et al may fall outside the scope of the claimed randomized linkers, the randomized linkers of Tang et al also fall

within the scope of the claimed randomized linkers and would necessarily contain the recited properties. Products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01. Additionally, the use of the randomized linkers of Tang et al for the production of scFvs in the plant expression system of Fiedler et al would necessarily produce scFvs that necessarily elicit an appropriate immune response. Again, in view of the combined teachings of Casper et al and Fiedler et al and Tang et al and Hakim et al, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have produced a scFv idiotype composition comprising an adjuvant, IL-2 or IFN-gamma wherein the VH and VL domains are obtained from lymphoma cells of a subject, linked by a randomized linker and produced using a plant expression system, which is identical to the presently claimed scFv idiotype composition (inclusive to an adjuvant such as IL-2 or IFN-gamma, particularly in view of claims 37-39) wherein the VH and VL domains are obtained from lymphoma cells of a subject, linked by a randomized linker and produced using a plant expression system. Therefore, it is the Examiner's position that Casper et al and Fiedler et al and Tang et al and Hakim et al have produced idotype-bearing scFvs that are identical to the claimed idiotype-bearing scFvs. One of ordinary skill in the art would reasonably conclude that the idiotype-bearing scFvs of Casper et al and Fiedler et al and Tang et al and Hakim et al also possesses the same

structural and functional properties as those of the idiotype-bearing scFvs claimed and, therefore, it appears that Casper et al and Fiedler et al and Tang et al and Hakim et al have produced idiotype-bearing scFvs that are identical to the claimed idiotype-bearing scFvs. Since the Patent and Trademark Office does not have the facilities for examining and comparing the claimed idiotype-bearing scFvs with the idiotype-bearing scFvs of Casper et al and Fiedler et al and Tang et al and Hakim et al, the burden of proof is upon the Applicants to show an unobvious distinction between the structural and functional characteristics of the claimed idiotype-bearing scFvs and the idiotype-bearing scFvs of the prior art. See In re Best, 562 F.2d 1252, 195 U.S.P.Q. 430 (CCPA 197) and Ex parte Gray, 10 USPQ 2d 1922 1923 (PTO Bd. Pat. App. & Int.). See MPEP 2112 and also MPEP 716.01 (i.e., unexpected properties, inoperability of the prior art).

Conclusions

15. No claim is allowed.

16. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Blanchard whose telephone number is (571) 272-0827. The examiner can normally be reached at Monday through Friday from 8:00 AM to 6:00 PM, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached at (571) 272-0832. The official fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,
David J. Blanchard
571-272-0827

SHEELA HUFF
PRIMARY EXAMINER